

As a patient who has used a compounded drug for the past 4 years I am greatly concerned and distressed regarding the negative impact that the MOU would have on myself and other patients. In my state there are no compounding pharmacies that make my particular prescription. By not allowing my prescription to be shipped your agency would be denying me use of my particular medication, which would have serious repercussions toward my health and functioning. No harm is being done to any person by continuing the practice of allowing prescriptions to be compounded and shipped from outside a patient's home state. Disallowing this practice however would result in hardship and unnecessary suffering for

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persons like myself.

These compounding pharmacies occupy a small but vital niche in our health care system. I urge your agency to act to protect the rights of patients like myself and the specialized pharmacies that serve us.

To the FDA:

RE: DOCKET NO. 98N-1265

I send this letter as a consumer of healthcare services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer, there should be no restrictions to the delivery of a compounded medication prescribed for me, regardless of where I may live or may travel. The MOU must be amended!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!

Signed:

Helen V. Goodman

State of Residence:

Rhode Island

Helen Goodman
18 Community Drive
Cranston, RI 02905



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Ln. Rm. 1061
Rockville, Md. 20857-0003

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